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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,153	07/08/2003	Masahide Ohyama	16822	8259
23389	7590	01/31/2006	EXAMINER	
SCULLY SCOTT MURPHY & PRESSER, PC 400 GARDEN CITY PLAZA SUITE 300 GARDEN CITY, NY 11530			PEFFLEY, MICHAEL F	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/615,153

Applicant(s)

OHYAMA ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-11, 14, 15, 17, 20 and 22-32 is/are rejected.
- 7) ☒ Claim(s) 5, 12, 13, 16, 18, 19 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All * b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/17/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Applicant's amendments and comments, received November 17, 2005 have been fully considered by the examiner. In particular, the amendments have overcome the 35 USC 101 and 35 USC 112, second paragraph rejections of claims 1-22. Also, the addition of newly filed claims 24-32 is acknowledged. The following is a complete response to the November 17, 2005 reply.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6-8, 10, 14, 15 and 22-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Goble et al (5,891,134).

Goble et al disclose an electrosurgical high frequency device that includes an RF generator (14) and active and return electrodes (24,26). Fluid is provided to the balloon to create a conductive path between the electrodes (see Abstract). Sensors are used to detect the current flow between the active and return electrodes to determine impedance, which impedance is used as an indication of the formation of vapor (i.e. bubbles) at the treatment site. Delivery of energy is controlled based on the sensed impedance to either maintain or avoid a vapor pocket (see columns 5 and 6). A controller controls the delivery of energy in accordance with the detected bubbles (i.e. vapor pocket). See column 6, lines 1-5, for example, which indicates the lowering of the energy once the impedance (i.e. bubble formation) has reached a particular level. This

recitation (i.e. the lowering of the energy upon detection of impedance indicating a vapor state) is deemed to read on applicant's claims 2 and 6-8. The "discharge promoting portion" recited in claim 10 is deemed to correspond to the end of the delivery tube of the Goble et al device which promotes the discharge of fluid to the electrode member.

Claims 1-4, 6-11, 14, 15, 17, 20 and 22-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Goble et al (6,210,405).

The Goble et al ('405) system is substantially analogous to the Goble et al ('134) device and includes active and return electrodes (16,18) disposed in a conductive fluid for the treatment of tissue (see Abstract). Again, Goble et al monitor impedance to determine vaporization of the fluid and control the delivery of RF energy based on impedance (i.e. bubble presence). See columns 9 and 10. Goble et al also teach that the flow rate of the fluid may be controlled in accordance with sensed conditions (col. 8, lines 55+). The electrode may take numerous shapes, including having apertures (Figure 2) or having a spiral shape (Figure 4), which shapes promote the generation of bubbles as fluid flows through the apertures and/or past the spiral.

Allowable Subject Matter

Claims 5, 12, 13, 16, 18, 19 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed with the November 17, 2005 response have been considered but are not deemed persuasive.

With regard to the Goble et al ('134) reference, applicant contends on page 13 of the response that Goble et al does not supply the RF current to the body anatomy but only uses the RF energy heat the bladder wall. The examiner disagrees. Goble et al specifically provide an embodiment, as shown in Figures 9A and 9B, that includes an open "cage" structure whereby fluid is delivered to the body space and RF current is delivered directly to tissue. Applicant also asserts at the bottom of page 13 and the continuation of page 14 of the response that applicant's claims requires the formation of a vapor pocket in the form of a plurality of bubbles covering the entire periphery of the electrode surface. The examiner has found no language regarding "bubbles covering the entire periphery" of the electrode surface. Rather, the claims recite that "bubbles are generated around the active electrode". The examiner maintains that bubbles would inherently be formed around the active electrode in the Goble et al ('134) device when the vapor pocket is created.

Concerning the Goble et al ('405) reference, applicant contends that there is no explicit teaching of controlling the delivery of RF energy based on the presence of bubble or impedance. Applicant does acknowledge that Goble et al ('405) mention that once the vaporization threshold has been reached, the power requirement falls. The examiner maintains that this disclosure is tantamount to disclosing the necessary means (i.e. sensor) to enable such a control. Moreover, Goble et al disclose the power

control function of the generator in column 12, lines 15-31, and indicate the more specific disclosure of such a power control is found in a related International Publication. Finally, the Goble et al ('405) disclosure and subject matter is substantially analogous to a large family of Goble et al patents (e.g. US Patent No. 5,891,134) which disclose the very well know use of sensors to control the output of a generator based on sensed conditions such as the formation of a vapor pocket and/or impedance. The examiner maintains that the Goble et al ('405) reference contains sufficient disclosure to anticipate the rejected claims.

Newly added claims 24-31 all recite limitations directed towards the intended use of the device. The Goble et al devices are deemed to be capable of acting in the same manner if so programmed. These claims fail to recite the specific structure and/or programming to specifically perform the intended use limitations.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

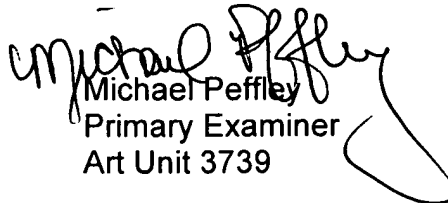
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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

mp
January 26, 2006